



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0567]

Design Considerations for Pivotal Clinical Investigations for Medical Devices; Guidance for Industry, Clinical Investigators, Institutional Review Boards and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Design Considerations for Pivotal Clinical Investigations for Medical Devices.” This document is intended to provide guidance to those involved in designing clinical studies intended to support premarket submissions for medical devices and for FDA staff who review those submissions. This guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements.

DATES: Submit either electronic or written comments on this guidance at any time.

General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “Design Considerations for Pivotal Clinical Investigations for Medical Devices” to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or the Office

of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to CDRH at 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. FOR FURTHER INFORMATION CONTACT:

For devices regulated by CDRH: Gregory Campbell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2110, Silver Spring, MD 20993-0002, 301-796-5750.

For devices regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

I. Background

The guidance document is intended to provide guidance to those involved in designing clinical studies that support premarket submissions for medical devices and FDA staff who review those submissions. Although the Agency has articulated policies related to design of studies intended to support specific device types, and a general policy of tailoring the evidentiary burden to the regulatory requirement, the Agency has not

attempted to describe the different clinical study designs that may be appropriate to support a device premarket submission, or to define how a sponsor should decide which pivotal clinical study design should be used to support a submission for a particular device. The guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements. The guidance is not intended to provide a comprehensive tutorial on the best clinical and statistical practices for investigational medical device studies.

A medical device pivotal study is a definitive study in which evidence is gathered to support the safety and effectiveness evaluation of the medical device for its intended use. Evidence from one or more pivotal clinical studies generally serves as the primary basis for the determination of reasonable assurance of safety and effectiveness of the medical device of a premarket approval application (PMA) and FDA's overall risk-benefit assessment. In some cases, a PMA may include multiple studies designed to answer different scientific questions.

The guidance describes principles that should be followed for the design of premarket clinical studies that are pivotal in establishing the safety and effectiveness of a medical device. Practical issues and pitfalls in pivotal clinical study design are discussed, along with their effects on the conclusions that can be drawn from the studies concerning safety and effectiveness.

In the Federal Register of August 15, 2011 (76 FR 50484), FDA announced the availability of the draft guidance. Interested persons were invited to comment by

November 14, 2011. FDA considered the comments and revised the guidance, as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on pivotal clinical investigations for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm> or <http://www.regulations.gov>. To receive "Device Considerations for Pivotal Clinical Investigations for Medical Devices," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1776 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of

Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under 0910-0120; the collections of information in 21 CFR part 812 have been approved under 0910-0078; the collections of information in 21 CFR part 814 have been approved under 0910-0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: November 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.